REMARKS

Status of the Claims

Claims 1-14 and 30-33 are pending in this application. Claims 30, 31, and 33 have been cancelled. Claim 32 has been amended to recite the unit of the ionic strength, mol/L for molarity as suggested by the Examiner. Support for this amendment can be found at page 19, Example 7, where it is disclosed that albumin solutions are prepared in purified water in a NaCl solution at 9 g/L with an ionic strength of 0.15. One skilled in the art would have understood that the **molarity** of the Nacl solution corresponds to 9/58= 0.15 mol/L, with the molecular weight of NaCl is 58 grams per mole.

No new matter has been added.

Claim Rejections Under 35 U.S.C. § 112

Claims 30-33 are rejected under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant submits that this rejection is moot due to amendments to claim 32 and cancellation of claims 30, 31 and 33.

Withdrawal of the corresponding rejection is thus respectfully requested.

Claim Rejections Under 35 U.S.C. §103

Claims 30 and 32 are rejected as being unpatentable over Ohmura *et al.* (EP 0 570 916), in view of Lengsfeld *et al.* (U.S. 2003/0232969) and Winge *et al.* (U.S. 6,399,357 B1). Applicant respectfully traverses. Reconsideration and withdrawal of the rejection are requested.

Claim 32 relates to "a virally safe aqueous albumin solution, in which the transport and binding sites of therapeutically active ingredients are available in the albumin, produced by a process that comprises steps a) and b).

As indicated by the Examiner, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.

The Examiner, states in the Office Action mailed August 31, 2011 on page 4 that the Applicant's arguments filed June 6, 2011 have been fully considered but they are not persuasive.

However, the Examiner simply discounts Applicant's arguments without discussing the new limitations added to the claims in Applicant's prior Response. (*i.e.* the transport and binding sites of therapeutically active ingredients available in the albumin).

In proceedings before the U.S. Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon prior art. To establish a *prima facie* case of obviousness, three basic criteria must be met. First the prior art reference, or references when combined, must teach or suggest all the claim limitations. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Finally, there must be a reasonable expectation of success.

In the present case the Examiner has not established (and cannot establish) that the cited prior art discloses all of the elements of claim 32. The Examiner has not shown that any of the prior art discloses an albumin wherein "the transport and binding sites of therapeutically active ingredients are available." Applicant's arguments relative to this rejection were made in the response filed June 6, 2011 and are hereby incorporated by reference. Applicant submitted a detailed analysis of Ohmura *et al.*, Lengsfeld *et al.*, and Winge *et al.* to show that a person skilled in the art would understand that they simply do not teach a pharmaceutical preparation comprising human serum albumin, free of acetyltryptophan or sodium caprylate that occupy the binding sites of the albumin.

On the contrary, it is clear from the teaching of Ohmura *et al.* that the pharmaceutical preparation of the recombinant human serum albumin contains acetyltryptophan or a salt thereof, and sodium caprylate:

> "*another object of the instant invention is to provide a pharmaceutical preparation comprising recombinant human serum albumin, acetyltryptophan or a salt thereof and sodium caprylate.*" (*see* EP 0 570 916, page 3, lines 15-16 and claim 11)

> "*The resulting pharmaceutical preparation consisted of 25% HAS, 0.02M acetyltryptophan sodium salt and 0.0M sodium caprylate.*" (*see* EP 0 570 916, page 16, example 10, lines 39-40)

It is also clear from the teaching of Winge *et al.* that the solution of albumin subjected to the filtration process was supplied by Pharmacia AB, Stockholm, Sweden (*see* column 12, lines 19-22), and was thus prepared through classical purification procedures possibly comprising a pasteurisation step in presence of stabilizers such as sodium caprylate. (*see* the enclosed Exhibit A confirming that this commercial product from Pharmacia (now Octapharm) contains caprylic acid, *i.e.* section 6 page 6). Thus, Winge *et al.* do not disclose the albumin solution as presently claimed.

Lengsfeld *et al.* (U.S. 2003/0232969) relates to the nanofiltration of protein solutions, by means of which it is possible to virtually completely separate off viruses. This object can be achieved by a method comprising adding to a protein solution at least one chaotropic substance. This document thus fails to teach a virally safe aqueous albumin solution in which the transport and binding sites of therapeutically active ingredients are available in the albumin.

Although the Examiner has urged that Applicant has only argued the differences between the prior art and the present application are so substantial that no combination of the references can be said to disclose all of the elements of Applicant's claim 32.

Claim 32 is, therefore, patentable over Ohmura *et al.* (EP 0 570 916), in view of Lengsfeld *et al.* (U.S. 2003/0232969) and Winge *et al.* (U.S. 6,399,357 B1), so the Applicant respectfully requests reconsideration and withdrawal of all outstanding rejections. Applicant submits that the claim 32 is now in condition for allowance, and respectfully request formal notification to that effect.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant respectfully petitions for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of $1,270.00 is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson Reg. No.

30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: February 28, 2012

Respectfully submitted,

By _____

Leonard R. Svensson
Registration No.: 30,330
BIRCH, STEWART, KOLASCH & BIRCH, LLP
12770 High Bluff Drive
Suite 260
San Diego, California 92130
(858) 792-8855
Attorney for Applicant

Enclosure(s): Exhibit A - Summary of Product Characteristics